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1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK

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3 UNITED STATES OF AMERICA, ex
4 rel. DAVID KESTER, et al.,

Plaintiffs and Relator,

v.

11 CV 8196 (CM)

7 NOVARTIS PHARMACEUTICALS
8 CORPORATION,

Defendants.

9 -----x

10 New York, N.Y.
11 March 14, 2014
9:30 a.m.

12 Before:

13 HON. COLLEEN MCMAHON,

14 District Judge

15 APPEARANCES
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(Case called)

THE COURT: This is not the way I like to do initial conferences, but this is not the typical case. Folks on the telephone, can you hear me.

VOICE: Yes, we can hear you.

THE COURT: Let me start by telling you two things. The first thing I will tell you is that, as my law clerks quickly learned, my brain is a triage operation. We insert exactly what it needs to know at any given moment in time. We deal with it, and it passes out.

For some substantial period of time, like two and a half years, this case was series of sealing orders. I've never read the complaint. I don't know what the details are. You're going to educate me, and then we're going to figure out how I can get it off my calendar in the next 12 months. Okay? So that's thing one.

Thing two is this is literally the first *qui tam* that I have had that has gotten this far, which is to say to a conference. I've had dozens of them. They're obviously the wave of the future. Every single one has ended up as a series of sealing orders and a settlement. So this is a new experience for me. Perhaps it's not a new experience for you. In that case, you'll be educating me doubly.

Now, who is here for the United States?

MR. YU: Your Honor, Li Yu.

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1 MS. MARTIN: Rebecca Martin.

2 MR. YALEN: Robert Yalen, your Honor.

3 THE COURT: And Ms. LaMorte.

4 MS. LaMORTE: Yes.

5 THE COURT: Good morning to the United States. Who is
6 here for the relator?

7 MR. SUBRAMANIAN: Your Honor, Arun Subramanian, from
8 Susman Godfrey, and Ms. Shelley Slade.

9 MS. SLADE: Vogel Slade & Goldstein, your Honor.

10 THE COURT: Good morning.

11 I know those two words. I know the word "relator" and
12 I know the words "United States."

13 Mr. Chesler, good morning. Mr. Chesler and I go back
14 a ways with Novartis. He came in and rescued a Novartis matter
15 that was tried before me some years ago, an employment
16 discrimination matter. It's good to see Cravath.

17 Who else is here from Cravath?

18 MS. SKAISTIS: Your Honor, my name is Rachel Skaistis.

19 THE COURT: Great. Who else is here for Novartis,
20 somebody else is here for Novartis?

21 MS. GAY: Good morning, your Honor. Faith Gay and
22 Manisha Sheth, from Quinn Emanuel.

23 MR. ROGOFF: Good morning, your Honor. Michael Rogoff
24 and Manvin Mayell of Kaye Scholer.

25 THE COURT: The first thing I need to know is why we

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1 have Cravath, Quinn Emanuel, and Kaye Scholer all for Novartis.

2 MR. CHESLER: I needed help, your Honor.

3 THE COURT: Fair enough, Mr. Chesler. That's a lot of
4 firepower.

5 From now on, I don't know who you people are. There
6 are a bunch of attorneys general who have intervened in this
7 matter, and that whole procedure needs to be explained to me.
8 But is there somebody who is going to speak for the attorneys
9 general so I'm not listening to 75? There aren't 75 states,
10 it's not possible.

11 MR. MILLER: Chris Miller, from the New York State
12 Office of the Attorney General. I can speak for myself and New
13 York and the states that are on the phone. Mr. Ross is here
14 from California as well and can speak for California.

15 THE COURT: How many states do I have?

16 MR. MILLER: You have 11 total. There are nine on the
17 phone.

18 THE COURT: Hello to the states that are on the phone.
19 If it's all the same to you, let's not do appearances. Okay?

20 Then I have CVS Caremark.

21 MS. MAINIGI: Enu Mainigi and Mandy MacDonald, from
22 Williams & Connolly, for CVS Caremark.

23 THE COURT: I don't know whether we're going to start
24 with the United States or with the relator, but now it's
25 time -- oh, excuse me.

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1 MR. GARDNER: That's all right, your Honor. We do
2 think of ourselves as the tail on this dog. Accredo and
3 Curascript, Allen Gardner and Daniel Meron, from Latham
4 Watkins.

5 THE COURT: Okay. I can't wait to find out who you
6 guys are. For the United States or for the relator, who is
7 going to tell me what this lawsuit is about?

8 MR. YU: Good morning, your Honor. Li Yu, for the
9 United States. I'm here to explain the government's case in
10 this matter. The government's case involves two kickback
11 schemes that Novartis orchestrated. And the nature of the
12 kickback schemes were that Novartis, as we allege, used
13 inducement in terms of money in the form of rebates as well as
14 patient referrals to turn health care providers, in this case
15 pharmacies, into tools for Novartis's marketing efforts.

16 THE COURT: Do me a favor and let's eliminate the
17 loaded words. As a result of having dealt with the employment
18 discrimination case involving Novartis, I learned a lot about
19 big pharma in a very short period of time. I learned a lot
20 about, for example, how pharmaceuticals are marketed. So let's
21 tell me exactly what it is that Novartis does that the United
22 States finds problematic.

23 MR. YU: Your Honor, two kickback schemes. The first
24 kickback scheme involves a transplant drug called Myfortic.

25 THE COURT: And what does it do?

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1 MR. YU: It's used post-transplant.

2 THE COURT: An antirejection drug?

3 MR. YU: Exactly, your Honor.

4 THE COURT: Okay.

5 MR. YU: And the core of the government's allegation
6 is that Novartis used pharmacies as part of these marketing
7 efforts. Specifically, it tied rebates, or the availability of
8 rebates to pharmacies to the pharmacists agreeing to recommend
9 to physicians that patients be switched on to Myfortic from a
10 competing drug.

11 THE COURT: Let me see if I get this. The government
12 alleges that Novartis marketed Myfortic to pharmacies and that
13 part of the deal was we'll pay you some money, we'll kick back
14 something, for every patient who you get to use this drug.

15 MR. YU: Your Honor, maybe I can break it down a
16 little bit more.

17 THE COURT: I think you need to break it down a little
18 bit more.

19 MR. YU: Will do, your Honor. Here, the basic
20 kickback is Novartis offered rebate contracts to pharmacies.

21 THE COURT: What does that mean?

22 MR. YU: Specifically that meant, for example, we will
23 just use one pharmacy, Transcript, which is based in
24 Mississippi, and, in that case, Novartis dangled the prospect
25 of Transcript getting certain levels of rebates so money back

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1 from Novartis, money back from Novartis, in terms of the sales
2 Transcript made of Myfortic.

3 THE COURT: If Transcript sold X amount of Myfortic,
4 it would get a certain amount of money in terms of a rebate
5 from Novartis?

6 MR. YU: Right.

7 THE COURT: If it sold twice that much, it would get a
8 larger rebate from Novartis.

9 MR. YU: In this case, the rebates were tied to the
10 market share. Let's say there are a hundred transplant
11 patients from Transcript, and they would all get transplant
12 drugs, some of which would be Myfortic, some of which would be
13 a competitive drug, so the rebate reflected how much Myfortic
14 was dispensed versus how much of the competitor drug was
15 dispensed.

16 THE COURT: And the idea was that it was wrong to
17 offer the rebate rate because that was a thumb on the scale for
18 the pharmacist and presumably in this world the pharmacist is
19 recommending to the physician what drug to prescribe. I
20 thought that's what the drug company reps did.

21 MR. YU: Your Honor, the allegation is not the rebate
22 contract itself. It's what is not disclosed and what's not
23 said in the rebate contract. It's the discussions that
24 happened prior. In order to get these rebate contracts,
25 Novartis had an arrangement or agreement with the pharmacy that

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1 in order to be a part of the rebate contract, the pharmacy
2 committed to recommending that patients be shifted from a
3 competitor drug to Myfortic. So it's the precondition for
4 getting the rebates.

5 THE COURT: Okay. So the pharmacists agreed that they
6 would recommend to the doctors who had the ultimate
7 prescriptive power, Why don't you try this Novartis product,
8 this is a great product, and the fraud is that the physicians
9 didn't know that there was a rebate involved? Is that why this
10 is problematic?

11 MR. YU: Your Honor, the physicians didn't know, A.
12 They did not know there was rebates involved, and they
13 certainly did not know that there was this preexisting
14 arrangement that's not disclosed.

15 THE COURT: Wait a minute. The preexisting
16 arrangement is that you're going to recommend my drug. It's
17 all of a piece. The physicians didn't know that there was a
18 deal between the pharmacy and Novartis that the pharmacist
19 would push the drug that was Novartis's drug.

20 MR. YU: Right, your Honor.

21 THE COURT: And the physicians were presumably
22 complete pushovers and they would do anything that the
23 pharmacists said.

24 MR. YU: Your Honor, here, because of the way the
25 recommendations were made, for example, they were made under

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1 the pretext of certain clinical justifications, and the result
2 was in many cases that patients were switched from a competing
3 drug to Myfortic.

4 THE COURT: To their detriment? Did they die, or did
5 they suffer rejection, at a higher rate?

6 MR. YU: Your Honor, I don't think the company would
7 dispute this, there is generally some risk whenever patients,
8 as we understand it, switch from one drug to another.

9 THE COURT: Listen, I would think there would be a
10 whole lot of risk when you get a transplant. I assume that
11 everything that happens after a transplant is not an experience
12 I'm eager to have.

13 MR. YU: Yes, your Honor. We agree completely. The
14 experience of getting a transplant is not a great experience.

15 THE COURT: I understand. But what I would like to
16 know is, is the reason that the United States has taken an
17 interest in this that there has been an increase in patient
18 morbidity as a result of this practice of pharmacists
19 recommending to doctors. I mean, the weird part of big pharma
20 marketing, which came out most clearly in the FLSA case, which
21 was not my case, is that you can't really sell a drug because
22 ultimately a doctor has to prescribe a drug, so the drug
23 representative who goes into the doctor's office isn't really
24 selling the drug, the pharmacist isn't really selling the drug,
25 the drug company isn't selling the drug to the doctor,

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1 ultimately there's a physician involved in this process, and
2 I'm trying to figure out where the fraud is.

3 MR. YU: Your Honor, let me answer that in two ways,
4 which is first is the fraud goes to the antikickback statute
5 itself. So paying a health care provider or offering
6 inducements, whether it's money or, in the Exjade case, patient
7 referrals to a health care provider, which pharmacies --

8 THE COURT: Patient referrals?

9 MR. YU: Your Honor, we'll get back to that point, but
10 focusing first on the money point.

11 THE COURT: Let's stick with the money.

12 MR. YU: Offering money or financial incentives to a
13 health care provider --

14 THE COURT: How about vacations to Hawaii?

15 MR. YU: Your Honor, certainly. Certainly, I mean,
16 here, that's definitely not the issue.

17 THE COURT: This is not that kind of a kickback.

18 MR. YU: There are other cases involving that, but
19 certainly money is an obvious instance of inducement or
20 incentive, so offering money to a health care provider for the
21 purpose of inducing that --

22 THE COURT: Influencing the health care provider's
23 decision.

24 MR. YU: Exactly. As your Honor said, put a thumb on
25 the scale in terms of what recommendations the health care

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1 provider makes, that is a violation of the antikickback statute
2 and that, in turn, gives rise to violations of the false claims
3 act.

4 THE COURT: I actually tried *qui tam* in maybe 2000
5 that involved a little operation in New Rochelle. It was
6 nothing like this. There weren't these massive attorneys
7 general and big pharma companies and the government wasn't a
8 relator and all of that, didn't intervene, they were just a
9 relator and all that stuff, so a very different situation. But
10 the false claims in that case had to do with claims that were
11 being submitted to Medicare. Now, is that where the government
12 comes in here?

13 MR. YU: Yes, your Honor. Here, the false claims were
14 submitted both to Medicare part B and part D, as well as to
15 Medicaid, which is why the states are here, because Medicaid is
16 a joint federal and state program, your Honor.

17 THE COURT: Yes.

18 MR. YU: Going back to your Honor's point earlier, so
19 unlike the pharmaceutical salespeople, here, the fraud is
20 problematic and it really goes to the heart of what the
21 antikickback statute is designed to, the types of conduct the
22 antikickback statute is designed to combat because the
23 recommendations are not coming from people who are obviously
24 working on behalf of the pharma company. Pharmacies are
25 generally they're supposed to act independently, and the nature

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1 of the scheme is that it makes them into part of --

2 THE COURT: It's interesting. It's a whole new
3 concept to me. One of my interns is on her way, because I'm
4 here with you, to Duane Reade for a prescription of Keflex
5 because I sliced my finger open last night and spent the night
6 in the emergency room. It's a prescription written by a
7 doctor. We're going to hand it to the pharmacist. The
8 pharmacist is going to hand us back a bottle of pills. So the
9 concept of a pharmacist making recommendations to a doctor, let
10 alone the concept that the doctor would listen, is kind of
11 foreign to me because that does not represent my dealings with
12 pharmacies.

13 MR. YU: Yes, your Honor, and just on that point,
14 here, both the Myfortic drug and the Exjade drug, which are the
15 two drugs --

16 THE COURT: Exjade, that's the other drug?

17 MR. YU: Yes, your Honor.

18 THE COURT: And what does it do?

19 MR. YU: It is a blood chelation drug. It basically
20 takes iron out of the blood system.

21 THE COURT: I thought there were all kinds of suits
22 against people who held themselves out as weird medical
23 practitioners because they did chelation therapy. This is a
24 good thing, chelation?

25 MR. YU: In this case, as a general matter, we are not

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1 disputing that patients who have too much iron in their body --

2 THE COURT: Okay. There is a drug to get rid of
3 excess iron. Okay.

4 MR. YU: Yes, your Honor.

5 Both Myfortic and Exjade are used to treat chronic
6 symptoms so they're not sort of going to the Duane Reade or
7 going to CVS, to take one of the parties here, to get a
8 prescription of a cold medication or something on a one-off
9 basis. And so in these cases, the pharmacies held themselves
10 out to be sort of specialty pharmacies as having more
11 expertise.

12 THE COURT: We're not talking before my neighborhood
13 drugstore, but we're talking about CVS. CVS is my neighborhood
14 drugstore up in Westchester.

15 MR. YU: Each of the pharmacies involved, either like
16 CVS, they're not a defendant in the government's case, may have
17 a specialty arm, so they have a division within their larger
18 corporate organization that's called a specialty arm, or they
19 hold themselves out to be a specialty pharmacy in the sense of
20 they specialize in certain types of drugs that are used to
21 treat long-standing conditions or chronic conditions.

22 THE COURT: You guys started this.

23 MR. SUBRAMANIAN: We did, your Honor.

24 THE COURT: Why?

25 MR. SUBRAMANIAN: Because, as Mr. Yu is describing,

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1 Novartis was absolutely prohibited from offering patient
2 referrals and rebates in exchange for the specialty pharmacies
3 going out and pumping Novartis drugs both to physicians and to
4 patients, and that's exactly what they were doing. And
5 specifically, your Honor asked why is the government involved
6 here. These are hard-core drugs, serious drugs with big
7 dollars attached, but also big consequences.

8 Just to give you one example. Exjade, which is one of
9 the drugs that Mr. Yu is talking about, has serious GI side
10 effects that have been described by the FDA. But if you look
11 at, for instance, the government's own complaint, Novartis was
12 providing talking points to the pharmacies so that when they
13 called up the patients -- and who are these pharmacists anyway,
14 what's their medical background? When they were calling up --

15 THE COURT: That's why I'm a little nonplussed by this
16 whole concept.

17 MR. SUBRAMANIAN: Right. That's exactly right.

18 When they were calling up patients, they were told to
19 tell the patients the side effects will pass and you should
20 continue taking Exjade. That's one example. You could
21 experience some discomfort initially, but it's usually resolved
22 over time. Now, why is that? Because under the
23 pay-for-performance scheme Novartis was orchestrating, they
24 were telling the pharmacies we're happy to give you patient
25 referrals.

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1 THE COURT: How does Novartis give patient referrals?
2 I assume I get referred by my doctor. It's all foreign to me.

3 MR. SUBRAMANIAN: Let me just give you the example of
4 Exjade. For about half the patients who are on Exjade, the
5 third-party insurer doesn't say which pharmacy will dispense
6 Exjade, and there are only three pharmacies that are authorized
7 to dispense the drug.

8 THE COURT: Oh.

9 MR. SUBRAMANIAN: So this goes through a hub, and it's
10 allocated out, so Novartis has a say-so in who is going to get
11 a prescription.

12 THE COURT: In other words, this is not Keflex.

13 MR. SUBRAMANIAN: Yes. It's not a drug you can get
14 filled at any random pharmacy. You can see the problem here is
15 that you have pharmacists and pharmacies who are going out and
16 pumping these drugs, according to the scheme Novartis
17 orchestrated. Why are they doing this? Because it's
18 absolutely profitable for Novartis to do this and it is very
19 profitable for the pharmacies to do this, and with respect to
20 Exjade, everyone should keep in mind BioScrip, one of the
21 pharmacies who is in this network -- there are only three, they
22 were one of them -- has already admitted to key parts of the
23 scheme and has settled out of the case. So that's where we're
24 and that's why we're here.

25 THE COURT: As I tell my juries when cooperators

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1 testify, a cooperator pleads guilty for whatever reason the
2 cooperator wants to plead guilty, it says nothing about the
3 guilt of anybody else. I mean, that's just one of the rules I
4 have to play by.

5 Mr. Miller, Mr. Ross, do you want to add something
6 here to educate me?

7 MR. MILLER: Your Honor, just so you know, the states
8 have intervened with respect to Exjade specifically, and, in
9 that regard, I'd just say that the Exjade scheme was really a
10 matter of corrupting the medical judgment of the pharmacy.
11 We've intervened as it pertains to Novartis's sales of Exjade
12 to the BioScrip pharmacy, and what we found in our
13 investigation and is in our complaint is that BioScrip was just
14 pushing the drug on patients -- that's a very dangerous drug --
15 without regard, without knowing the precise medical conditions
16 that the patients had, without knowing, for instance, their
17 iron levels and whether they really needed the drug or whether
18 they were on the cusp of having the drug, told them to keep
19 taking it and that the side effects would --

20 THE COURT: Isn't that the response, there's got to be
21 a prescribing physician somewhere. That's what I'm kind of
22 mystified by. If Novartis were corrupting the prescribing
23 physician, I think I would have an easier time with this, but
24 you're saying that it's the pharmacist who was corrupted and
25 somehow that managed to translate into a prescribing

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1 physician's prescribing a drug.

2 MR. MILLER: The physician indeed had to initially
3 initiate the prescription, but for refills, the pharmacy was
4 tasked with calling the patients and arranging for the refills
5 under the contracts with Novartis, and, for instance, in the
6 State of New York, the patient needs, under New York State
7 Medicaid rules, to agree to accept a refill. So you have the
8 pharmacy convincing the patient to take the refill and a lot of
9 these people were very sick.

10 THE COURT: The refill is of a drug, but the
11 pharmacist can't substitute. This is not something with a
12 generic drug, I assume, where you have a little thing on the
13 prescription pad that the doctor has to check it, otherwise it
14 can be filled by a generic. I'm assuming that this Exjade
15 stuff doesn't have a generic equivalent. So it's a refill of a
16 prescription that was written by a pharmacist, and is there an
17 ability of a pharmacy to substitute a different drug without
18 the intervention of a physician?

19 MR. MILLER: No, but they need to get the approval of
20 the patient to take the refill and I think it's important to
21 understand the clinical circumstances.

22 THE COURT: They need to get the approval of the
23 physician to change the drug from whatever Exjade's competitor
24 is to Exjade, right?

25 MR. MILLER: But the issue is whether or not the

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1 patient is going to take the refill of Exjade, not some other
2 drug. The Myfortic scheme is a switching scheme. The Exjade
3 is a refill scheme in which the pharmacy was trying to convince
4 the patient to take the refill. The thing that's important to
5 understand is that for Exjade, people come off this drug very
6 rapidly. After six months, often 50 percent of people are no
7 longer taking the drug, in part, because they're having lots of
8 medical problems and they're having side effects from Exjade
9 itself.

10 THE COURT: If there's a refill, it's because the
11 doctor wrote the prescription and said you can have three
12 refills, right?

13 MR. MILLER: The doctor did, but the patient has the
14 right to refuse the prescription refill and often the patients
15 did because of the side effects of the drug. So you often have
16 people, and in particular in this scheme, Novartis promoted
17 Exjade to a group of patients who heretofore had not typically
18 taken the predecessor drug for this condition and promoted it
19 to people who were very sick, often many of whom died shortly
20 after commencing therapy on the drug, and so they were making
21 key decisions about how to live the last days of their lives.
22 They were deciding whether they wanted to live the last days of
23 their lives throwing up or vomiting or not, so they needed to
24 make an informed decision about whether to take that refill or
25 not, and instead they got advice from LPNs who were untrained

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1 in the conditions they had, untrained with respect to Exjade,
2 who basically told them, Take the drug or you'll die and don't
3 worry, the side effects will go away if you continue taking the
4 drug.

5 THE COURT: Mr. Ross, the states are not in the
6 Myfortic; they're just the Exjade?

7 MR. ROSS: That's correct, your Honor, and we've
8 intervened just as to Exjade.

9 THE COURT: Okay. Let's go to the back table.

10 Mr. Chesler.

11 MR. CHESLER: Yes, your Honor.

12 THE COURT: I assume there's another side to the
13 story.

14 MR. CHESLER: There is, your Honor.

15 THE COURT: Okay.

16 MR. CHESLER: We disagree with both the theory of the
17 government's case and the facts. Let me start with the theory,
18 and let me start with Exjade. As the government explained to
19 you, Exjade is a drug that removes excess iron from the blood.
20 It's typically taken by patients who have chronic diseases that
21 require multiple blood transfusions. And as they are
22 transfused with blood, over time, excess iron builds up in
23 their bloodstream. It is a silent killer.

24 THE COURT: Too much iron in the blood.

25 MR. CHESLER: Yes. It destroys organs, kidneys, etc.,

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1 and it's not the kind of thing where you have a pain in your
2 stomach and you go to the doctor and he says you ate some bad
3 food or something. You don't necessarily have any symptoms at
4 all and you're being treated for some other disease, for
5 example, sickle cell anemia, which is a chronic disease that
6 requires transfusions for very long periods of time. As that
7 process is taking place, the patient is suffering with sickle
8 cell anemia, but iron is building up in her bloodstream as a
9 result of it. What Exjade does is remove the iron in the blood
10 over time through this chelation that was mentioned. Here's
11 the problem. If the patient doesn't adhere to the drug, then
12 the iron begins to build up again, and there are side effects
13 and these patients are very sick. And they're not suffering
14 the direct consequence of the iron buildup. They don't know
15 about that. Their organs know about it, but they don't. And
16 so compliance or adherence is critical.

17 To go back to a point that your Honor was on with all
18 of the lawyers for the plaintiffs, the doctors are the ones who
19 write these prescriptions. The doctors are the ones who
20 determine whether their patients should be taking a drug at all
21 and, if so, which drug. The specialty pharmacies provide
22 advisory services, counseling services. They're not just
23 walking in off the street to the CVS with a script from your
24 doctor, take the bottle and leave. They provide these
25 auxiliary services. There's nothing illegal about that.

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1 Indeed, they're good things about the world because they give
2 people information. But it is the doctors who decide.

3 The problem we have with the government's theory,
4 first of all, is they're trying to convert an adherence
5 program, and there will be, your Honor, when we get to the
6 evidence eventually, a ton of evidence to show that the
7 government itself proclaims the virtues of adherence programs
8 because if people don't take drugs for chronic diseases, they
9 get sicker, and the government wants people to be well as does
10 my client, and if they stop taking the drug, it's not good for
11 them. So the government, in the Exjade situation, is trying to
12 convert an adherence program into a kickback scheme. And in
13 the case of Myfortic, they're trying to claim that doctors
14 aren't the ones who decide whether their patients should switch
15 drugs or not, it's the pharmacies that do. We believe that
16 will not be supported by the factual evidence. And they're
17 trying to convert a situation in which people are given
18 discounts -- that is, the pharmacies are given discounts --
19 which are specifically permitted by the law. There is a
20 statutory safe harbor for discounts because, in fact, the
21 government wants drugs to be cheaper.

22 THE COURT: I don't know the antikickback statute at
23 all, so I have to familiarize myself.

24 MR. CHESLER: I understand, your Honor. Again, I'm
25 just giving you our view of the case both on the theory and

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1 factual basis, and we believe in both instances the government
2 is engaged really bad enforcement policy. This is not trips to
3 Hawaii for somebody who is pushing drugs on unsuspecting
4 patients that they would otherwise not take. If these patients
5 don't take these drugs, they will die. These are not cold
6 medicines, these are not aspirins. These are drugs that are
7 critical, lifesaving drugs. The prescriptions are written by
8 the doctors. The pharmacies provide the drugs to the patients,
9 as they do with respect to most drugs.

10 So we think that there's a fundamental flaw in the
11 government's theory here, and there's also, as I said, a
12 fundamental flaw in the facts. We moved with respect to the
13 government's complaint under 9(b). We haven't moved yet on the
14 relator complaint because the date hasn't come yet, but we
15 will. And the fundamental factual problem here is that there
16 are broad sweeping allegations with nothing remotely like the
17 specifics that the law requires, that Rule 9(b) requires.

18 THE COURT: Yes, but, Mr. Chesler, I hate 9(b)
19 motions.

20 MR. CHESLER: Your Honor, so do I, and I've passed up
21 a lot of opportunities to make them over the years, but I tell
22 you with all sincerity, trying to defend these complaints
23 without the specifics, let me give you an example. There is
24 not any allegation here of any doctor whose prescriptions were
25 changed as a result of this scheme that they're alleging.

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1 THE COURT: This is Myfortic.

2 MR. CHESLER: Take either one of them, either one.

3 The states, as they said, only relate to Exjade. The federal
4 government complains about both drugs. The relator complaint
5 is both drugs plus three other drugs that haven't been
6 mentioned yet.

7 There are no allegations. Who are the doctors who
8 listened to some pharmacist? My son is a surgeon, he's a brain
9 surgeon. He's a smart kid. He doesn't take his prescription
10 advice from pharmacists, with all due respect. He went to
11 medical school to learn how to do that. Surgeons who do
12 transplants, who put new organs in people's bodies, make their
13 own determinations about what drugs their patients should take,
14 not the pharmacists. The fact that there are prescribing
15 decisions being made by doctors is the way the system's
16 supposed to work. So we need the specifics. We've moved for
17 the specifics because when you see, you mentioned you haven't
18 read the complaints, and obviously I know you will in due
19 course, they're voluminous.

20 THE COURT: Real soon.

21 MR. CHESLER: They are voluminous in length, they are
22 heavy in weight, they are vacant in substance. There are a lot
23 of adjectives and adverbs, there are a lot of sweeping
24 allegations. When you get down to the basics we all learned
25 about who, what, where, when, and why, they're not there.

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1 We've been telling the government there for months. We moved
2 before Judge Gardephe in other kickback litigation and he
3 called the plaintiffs in and said I don't see the specifics
4 here, they had to amend their complaints, and we're still
5 litigating about that over there. These are not complaints
6 that is pass Rule 9 muster, so we have both a theory problem
7 here and we have a fact problem here.

8 THE COURT: That is why I asked, for example, if the
9 genesis of the government's interest here was an increase in
10 patient morbidity because of switching drugs or something like
11 that.

12 MR. CHESLER: No, your Honor, not as far as I know.
13 No.

14 THE COURT: Okay.

15 MR. CHESLER: As I said, if you are unfortunate enough
16 to have to have an organ transplanted, you have to take
17 immune-depressant drugs so that the organ is not rejected. My
18 client makes Myfortic. Other people make other drugs.
19 Obviously, my client wants to sell its drug; it spent a lot of
20 money to invent it. It wants to make a profit on it. But
21 there is, we believe, nothing illegal in what they did here.
22 Your honor said, when you took the bench, you have had a lot of
23 *qui tam* cases, they are sealed and then they settle. The
24 reason we are here and it didn't follow that path, the reason
25 I'm here, is because this isn't those cases, this isn't the

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1 trips to Miami on some boondoggle push some more of my pills.
2 This is overreaching, with all respect to my government. It's
3 overreaching, and that's why we're defending ourselves. And
4 that's why there are a lot of lawyers standing behind me,
5 because we care about this. This is an attack on the
6 fundamental part of our client's business, and we're standing
7 here to defend ourselves.

8 I'm happy to answer any questions, your Honor.

9 THE COURT: Before I get to you, you all have more
10 drugs? In Mr. Chesler's case, there's more drugs?

11 MR. SUBRAMANIAN: That's correct, your Honor. There
12 are three additional drugs. TOBI, which is a cystic fibrosis
13 drug, and that's a respiratory illness, and TOBI is a drug
14 that's used to address that. And there are two additional
15 drugs are Gleevec and Tesigna.

16 THE COURT: I know what Gleevec is.

17 MR. SUBRAMANIAN: Those are both oncology drugs to
18 treat leukemia and some other illnesses.

19 THE COURT: Is it an Exjade theory or a Myfortic
20 theory?

21 MR. SUBRAMANIAN: More along the lines of the Exjade
22 theory.

23 THE COURT: I've got to tell you, Mr. Miller, I think,
24 got it into my head, but I'm not sure I'm quite clear. If a
25 doctor has prescribed a medication and has prescribed it for

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1 over a period of time so that there are refills, presumably
2 until the patient goes and sees the doctor the next time, what
3 business is it of the pharmacist to try to talk the patient out
4 of refilling the drug? I don't understand that so I'm
5 obviously missing something.

6 MR. SUBRAMANIAN: Let me give you an example. For
7 instance, Exjade, which we've been talking about a little bit,
8 is a drug that's used to address the side effects that often
9 occur when you have a transfusion. But, of course, you're not
10 having a transfusion all the time. You have a transfusion and
11 you may need some treatment for that. What was happening is
12 that patients were not taking Exjade on a permanent basis.
13 It's something they would need for a short period of time.

14 THE COURT: That's up to the doctor, right?

15 MR. SUBRAMANIAN: Right.

16 THE COURT: That's up to the doctor.

17 MR. SUBRAMANIAN: Exactly right.

18 THE COURT: So the doctor writes a prescription for
19 two months worth of Exjade with two refills, which presumably
20 means the doctor has made a judgment that the patient should
21 take it for six months.

22 MR. SUBRAMANIAN: Right. But in 2007, Novartis came
23 to know, they understood doctors were not refilling. Patients
24 were going back to doctors and saying I don't need the refills
25 and doctors were saying you don't need the refill because of

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1 the side effects of Exjade, so Novartis said let's try to short
2 circuit that process. Let's have the pharmacist call the
3 patient and when they're told I'm having side effects about
4 these drugs, they're told those will pass, you still need to
5 refill the drug.

6 THE COURT: And then the patient goes back to the
7 doctor and says I was wrong, I really do need more? And the
8 doctor says, Oh, sure, okay?

9 MR. SUBRAMANIAN: One, they're not going back to the
10 doctor. That's exactly the problem.

11 THE COURT: Then there's no refill, if the doctor
12 hasn't written a refill. That's where I'm missing. There's a
13 fact somewhere that I'm missing, that I'm not understanding
14 because the pharmacist can't refill the prescription unless a
15 doctor says you can refill the prescription.

16 Mr. Yu, what am I missing?

17 MR. YU: Your Honor, the question, here, first of all,
18 just focusing on the Exjade, the way the scheme operated was
19 Novartis used these incentives to induce BioScrip to make, it's
20 not a patient coming to BioScrip to pick up some prescriptions;
21 BioScrip made affirmative calls using its staff to patients to
22 try to push these refills.

23 THE COURT: But that means a doctor has written a
24 refill. The doctor has already said refill the prescription.
25 Presumably BioScrip, they're not here, calls up the patient and

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1 says time for your refill. The patient says I don't want the
2 refill, BioScrip says time for your refill, you need to take
3 this drug, this drug will be good for you. Doesn't the patient
4 have to go back to the doctor?

5 MR. YU: Your Honor, that's actually a critical point.
6 As I think Mr. Miller had said earlier, in fact, as BioScrip
7 stipulated, the practice was the patient had to actually order
8 that refill before the refill can be shipped to patient. So
9 the point of the scheme is that it's a recommendation for the
10 patient to order this refill.

11 THE COURT: I understand. But this is where I'm
12 having a problem, because the doctor has already directed the
13 patient to take the refill of the drug. I'm playing devil's
14 advocate, but I'm missing something. I'm trying to get what
15 I'm missing. You're saying that the pharmacist had no right to
16 tell the patient to do what the doctor said, the pharmacist, in
17 fact, should have allowed the patient to override the doctor's
18 judgment because the patient thought the patient would feel
19 better?

20 MR. YU: Your Honor, there are two basic issues.

21 THE COURT: What am I missing?

22 MR. SUBRAMANIAN: Your Honor, if I could clarify, the
23 doctor doesn't say I order you to take the refill, and the
24 doctor also doesn't need to be contacted when the actual refill
25 is made.

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1 THE COURT: I understand that, because the doctor has
2 already made in advance a judgment that the prescription should
3 be refilled three times.

4 MR. SUBRAMANIAN: Sometimes I'll go to the doctor and
5 I'll get a prescription for a drug, and the doctor says I'm
6 going to authorize you to have some refills if you need it. If
7 you need it.

8 THE COURT: And do we have facts, do we have evidence
9 that there are doctors who are going to get up here and they
10 are going to testify I told my patient I'm going to authorize
11 three refills if you need it for this kind of drug? I know
12 enough about transplants to know that that ain't the case with
13 antirejection drugs. Antirejection drugs you take for life, so
14 it's not a question of you can have a refill if you need it.
15 It's a question of you have a refill. So if, as you tell me,
16 this is not like Keflex, these are special drugs for special
17 conditions, then I'm having a hard time with the
18 you-can-have-a-refill-if-you-need-it argument.

19 MR. YU: Your Honor, not only is there going to be
20 evidence of doctors saying that, Novartis itself is aware, and
21 we specifically allege this in the complaint, that a
22 significant number of doctors, once they become aware that
23 patients were having these serious symptoms and side effects,
24 in fact, directed the patients to discontinue. So the doctor
25 may say I'm telling you that you have to take this drug for six

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1 months and then as patients began to report side effects, then
2 the doctors would then say, Okay, the side effects are serious
3 and you should stop taking, now the cost-benefit analysis has
4 shifted.

5 THE COURT: And so now that the problem is that the
6 doctor says I know I gave you a refill, but this is causing you
7 problems so don't refill the prescription, the pharmacist says,
8 no, no, no, you've got a refill on this, take your refill, and
9 the patient listens to the pharmacist and not the doctor?

10 MR. YU: Your Honor, because BioScrip in this case, in
11 the government's complaint, is affirmatively calling up
12 patients and, in fact, using these talking points that talked
13 up the benefit of the drug and basically said the side effects
14 are manageable, it effectively circumvents the whole problem.
15 If a health care professional tells the patient you may be
16 having side effects but they're going to go away, so what you
17 create --

18 THE COURT: Maybe I should not put myself in this
19 because I wouldn't listen to anything a pharmacist said if my
20 doctor told me not to take the drug. Guess who wins in the
21 great hierarchy of things? The doctor. The doctor trumps the
22 pharmacist every time.

23 MR. YU: Your Honor, taking a step back, the core of
24 the allegation here is Novartis offered and paid significant
25 sums of money and gave patient referrals, which you've heard

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1 from relator counsel, as part of these schemes and these were
2 done because the scheme involved here, the kind of conduct
3 involved here had an effect. In the complaint, we talked about
4 what they call a return-on-investment analysis that Novartis
5 made.

6 THE COURT: But everybody who develops problems makes
7 an ROI.

8 MR. YU: But here the ROI is not on the product
9 itself. It's on the specific practices the government is
10 targeting here, which we're addressing as kickbacks, which
11 themselves are illegal, and not only are they themselves
12 illegal, because the antikickback statute is so important, a
13 pharmacy, for example, that participates in Medicare part B are
14 required to sign certifications that say --

15 THE COURT: That's why you're here. That's how you
16 get the false claim.

17 MR. YU: Exactly, your Honor, because the antikickback
18 statute is such an important part.

19 THE COURT: So the issue then is whether the practice,
20 whatever it is, falls within the safe harbor of the
21 antikickback statute or not? Is that the ultimate legal issue
22 in the case?

23 MR. YU: Your Honor, insofar as Novartis wants to
24 claim safe harbor, they can certainly claim the defense.

25 THE COURT: They will.

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1 MR. YU: Your Honor, I think Mr. Chesler made that
2 plain.

3 THE COURT: If he hadn't, you know they would.

4 MR. YU: We fully expect that.

5 THE COURT: Is that the ultimate legal issue?

6 MR. YU: On the Exjade, we don't think the patient
7 referral aspect of the case falls into any safe harbor
8 whatsoever. So, here, to really bring this together, you have
9 a system, based on the way the government believes the evidence
10 will shape up, that Novartis gave incentives to a pharmacy so
11 the pharmacy would have its employees, who are not trained,
12 call out, give patients advice.

13 THE COURT: They're trained, but they're not doctors.

14 MR. YU: Not only were they not doctors, they were not
15 actually even trained on the very drug they were supposed to be
16 advising and counseling patients on, your Honor.

17 THE COURT: So why is the patient listening to them
18 instead of the doctor? Are we dealing with a particular
19 patient population? I know enough about that to know that it
20 strikes disproportionately in the minority community. Does
21 that mean we're talking about a patient population that is
22 somehow less adept in dealing with medical professionals and
23 thinks it's okay to listen to a pharmacist as opposed to a
24 doctor?

25 MR. YU: Your Honor, again, going back to the

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1 antikickback statute, it's not about any specific population or
2 any specific demographic. That's certainly not an issue. The
3 issue is the pharmacies are calling out under the guise of
4 being a neutral, independent health care provider. They are
5 contacting patients, offering counseling, and offering advice,
6 and the way the patient referral, what we view as a kickback
7 scheme operated is ultimately Novartis gave more patients
8 funneled more patients to BioScrip as part of the kickback so
9 that more patients were exposed to one-sided, bad counseling
10 about the side effects.

11 THE COURT: Novartis may be the most evil company in
12 the world, but Novartis can't refer a patient to a pharmacy
13 because Novartis can't prescribe a drug. Somewhere, there's
14 got to be a doctor in this process, and I don't understand. I
15 know I have to filter my own personal experience in dealing
16 with doctors and pharmacies out and I don't have a disease that
17 requires any of these kinds of drugs. But you talk about
18 patient referrals, and Novartis manufactures pharmaceuticals,
19 they don't treat patients. So how do they refer patients?

20 MR. YU: Your Honor, let me briefly explain that and
21 come back to the main point. On the Exjade drug, Novartis
22 created a hub so all of the Exjade patients or almost all of
23 the Exjade patients who are prescribed Exjade --

24 THE COURT: By a doctor.

25 MR. YU: By doctor.

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1 -- were funneled through this hub.

2 THE COURT: That I understand. That's marketing.

3 We're going to handle our marketing in a way that's efficient
4 for us. We're going to handle it through three pharmacies and
5 we're going to make sure that we have talking points for those
6 people and all of that. But it's not referring, it starts with
7 the doctor.

8 MR. YU: Your Honor, it may start with the doctor, but
9 the antikickback statute is very clear. At no point within the
10 health care system does a drug company give incentives, pay
11 money, or give other incentives to a health care provider for
12 the purpose of driving recommendations. So Novartis can have
13 its own marketing force, it can have its own sales force, but
14 these are separate pharmacies. They stand on their own. Not
15 only are they separate pharmacies, they're supposed to be
16 independent health care providers, and to pay, to give
17 incentives to someone who is supposedly holding themselves out
18 to be independent health care providers, in order for them to
19 recommend a drug, whether to a doctor or to a patient, that
20 violates the antikickback statute, your Honor. And that
21 violates the certifications that these pharmacies themselves
22 submitted as part of their participation.

23 THE COURT: Mr. Chesler, you're getting up.

24 MR. CHESLER: Your Honor, may I make one other
25 comment, please.

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1 THE COURT: Sure. Then we'll talk procedure.

2 MR. CHESLER: It occurs to me, as I'm listening to
3 counsel, that there is a critical place where our theory
4 problem and our fact problem converge, and I just want to plant
5 this thought with your Honor. The statute requires that a
6 false claim must have resulted from the allegedly unlawful
7 scheme, resulted from. It requires causation. That's the
8 problem, I submit, with the government's theory in these cases
9 and the relators' theory. And it's the problem with the
10 pleadings, the defects in pleadings that our motion is directed
11 at. Your Honor, I don't think, has heard yet today any
12 evidence.

13 THE COURT: I haven't heard any evidence.

14 MR. CHESLER: Or any allegation of any evidence of
15 claims actually resulting from, false claims resulting from the
16 scheme, and this relates to the fact that the docs are the ones
17 who make these prescribing decisions.

18 THE COURT: I understand what the government's and the
19 relators' and Attorney Generals' theory of causation is. I
20 mean, I know how they intend to argue resulting from. What I
21 was trying to figure out was if this case was going to distill
22 down to a legal issue, which is whether your client's marketing
23 practices *vis-a-vis* pharmacies *vis-a-vis* these drugs fall
24 within the safe harbor or don't fall within the safe harbor.
25 That's the legal question.

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1 MR. CHESLER: That will be a legal question. I don't
2 think it will be the only legal question, and that's why I make
3 the resulting-from point, because the case law, and there have
4 been a number of these cases now decided on the district court
5 level in other circuits, not in ours, but the case law very
6 often revolves around whether the facts have, in fact,
7 demonstrated that causal relationship. It's not enough to say
8 there's an alleged scheme and there were prescriptions written
9 and there were drugs sold. They have to link them.

10 THE COURT: And there were certifications made to
11 Medicare.

12 MR. CHESLER: Right.

13 THE COURT: For every one of those prescriptions,
14 which they say resulted from, which is why I don't understand
15 how the pharmacy/patient relationship could have resulted in
16 the writing of a prescription unless we're talking about a
17 large group of patients who do the equivalent of watching
18 commercials on television and then going their doctor and
19 saying I need X.

20 MR. CHESLER: Please give me Myfortic.

21 THE COURT: I need Myfortic. You know what I mean.

22 MR. CHESLER: I know exactly what you mean. It is at
23 the detail level.

24 THE COURT: I need Andro T. That seems to be the big
25 one these days, I need Andro T. I don't, not me. Not me.

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1 MR. CHESLER: It is at that detailed level of actually
2 showing that actual false claims resulted from the alleged
3 scheme.

4 THE COURT: Oh, goody, I'll have a trial. That will
5 be exciting.

6 MS. MAINIGI: Your Honor, before you get to procedure,
7 I just wanted to jump in with respect to CVS.

8 THE COURT: Yes, I should talk to the pharmacies.

9 MS. MAINIGI: We agree with you, your Honor, that the
10 doctor writes the prescription and the doctor is ultimately in
11 charge.

12 Just to talk procedure for one second here, the
13 government has a complaint in intervention. It is only against
14 Novartis. There is a relators complaint where the government
15 presumably investigated the allegations, as they're statutorily
16 obligated to do, and they made a nonintervention decision.
17 Relators then proceeded and filed another complaint which
18 includes Novartis, but it also includes us as well as the other
19 pharmacies. And I think it's pretty telling that the problem
20 we have is the same one that Mr. Chesler has, which is when the
21 other side gets up and talks about the specifics that you're
22 asking for, they keep going back to BioScrip, BioScrip,
23 BioScrip. BioScrip's not here. They settled out of this case.
24 There are other pharmacies here, and the problem that
25 we have with this complaint is that there are no specific

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1 allegations against any of these pharmacies with respect to
2 what they did.

3 THE COURT: Other than BioScrip.

4 MS. MAINIGI: And BioScrip is gone. There's nothing
5 here, and that's why for us a motion to dismiss on 9(b)
6 allegations is very significant. And I do a lot of work in
7 this particular area, the False Claims Act area. It is an area
8 where 9(b) has a lot of teeth and a lot of bite because you've
9 got a wave of relators just filing cases that may not really
10 cut it in the federal system. Ultimately, I can't tell you
11 what this case is about as it relates to us because I don't
12 have the specific allegations to be able to digest it in the
13 context of what my client does and their place in the
14 health-care delivery system.

15 I understand rebates are perfectly fine. I agree with
16 that. Everybody knows about rebates. They'd been litigated
17 about 15 years ago, as to whether they are kickbacks. What
18 they say is, it's what the discussions were beforehand, and the
19 stuff that got discussed between Novartis and the pharmacies,
20 there's nothing in there about CVS Caremark in any discussions
21 that were had with Novartis.

22 THE COURT: You want to say something on behalf of
23 your pharmacy.

24 MR. GARDNER: One quick thing, your Honor. I would
25 echo what you just heard from CVS. We're in the decline case

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1 only, my two clients Accredo and Curascript.

2 THE COURT: Decline.

3 MR. GARDNER: Meaning the government's not in our
4 case.

5 THE COURT: The relator has five drugs and three
6 defendants and the government, collectively --

7 MR. CHESLER: Four defendants, your Honor.

8 MR. GARDNER: I represent two defendants, your Honor.

9 THE COURT: Five drugs, four defendants. The
10 government, collectively, have two drugs, one defendant. So
11 we've got two sets and there's overlap. I'm right about that?

12 MR. CHESLER: Yes.

13 THE COURT: I've done my venn diagram?

14 MR. GARDNER: Yes, your Honor. Now you know which
15 circle we fall under?

16 THE COURT: Now I know which circle you fall under.

17 MR. GARDNER: The only thing I would like to add we,
18 too, will be filing a 9(b) because the only allegation that we
19 can divine from the complaint is that we called patients when
20 their refills from their prescriptions that they got from their
21 physicians were coming up due and we needed to know whether to
22 dispense the pills and ship them or not, which is something
23 that the FDA actually encourages, and missing doses of some of
24 these drugs --

25 THE COURT: I wish people in my husband's insurance

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1 plan would do that for me because I always get down to the last
2 pill --

3 MR. GARDNER: If you'd like to switch.

4 THE COURT: But I think that the government's
5 alleging -- the governments are alleging -- that you do a lot
6 more than just make that call and say, Oh, your prescription is
7 coming due. I think they're alleging that your people say more
8 than that.

9 MR. GARDNER: If they are, your Honor, we'd sure like
10 to see it in the complaint so we know what we're responding to.

11 THE COURT: Can I offer a suggestion?

12 Have a seat. Two procedural things suggest themselves
13 to me, one we are certainly going to do. You can forget about
14 the other three drugs because we're not going to litigate about
15 them right now. We're going to litigate about them now; we'll
16 get to them eventually.

17 Second, I'm quite capable of reading the complaint
18 with a 9(b) eye. Why do your clients need to spend a lot of
19 money on motions? You make your motions, you say the
20 complaints are defective under 9(b), I'll read the complaints,
21 I'll let you know. Then we'll know if we have to amend the
22 complaints to allege with more particularity or not. That
23 tends to be how I decide 9(b) motions, just by reading
24 complaints. Briefs aren't very helpful. I know the law.
25 Might save myself some taxpayers' dollars, at least Mr. Miller

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1 and the government, the government, the big G government. I
2 don't care about California. My son would like me to.

3 MS. MAINIGI: Your Honor, I believe that there is a
4 date in the record right now for motions.

5 THE COURT: When is it.

6 MS. MAINIGI: It's April 21, your Honor.

7 THE COURT: Yes, but I don't want to wait because in
8 12 months, we're going to have a trial date, April 1, 2015. I
9 don't want to wait. I want to move. I've been waiting for
10 three and a half years. My time has come.

11 MS. MAINIGI: We would like to get out of this case as
12 soon as we could, your Honor.

13 THE COURT: You're not going to get out on a 9(b)
14 motion. They're going to amend.

15 MS. MAINIGI: I don't know.

16 THE COURT: And I only give them one shot. If they
17 haven't alleged enough and they can't allege enough the next
18 time around, it's bye-bye. And otherwise, you don't have a
19 whole lot of time to do discovery.

20 MS. MAINIGI: Your Honor, if I may.

21 THE COURT: One of the problems that I have with these
22 cases, I'm sorry to interrupt you. One of the problems I have
23 with these cases --

24 Is this the case where I finally told the government
25 *no mas*?

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1 MR. YU: Yes, your Honor.

2 THE COURT: This is the case where I finally said no,
3 I'm not signing another sealing order. They take forever, but
4 they're still on my docket. They get counted against me in
5 some statistical base in Washington because, as far as the
6 Administrative Office of the United States Courts, is
7 concerned, I should have had this case closed 18 months ago.
8 They sit around and they sit around and they sit around and
9 they sit around, and nothing happens. So when I finally said
10 fish or cut bait, and the government decided to fish, the
11 governments decided to fish, this case isn't going to take two
12 or three or four years to litigate. I'm going to look for ways
13 to expedite. I'm not going to wait. Now that you're here, I'm
14 not going to wait until April 21 for you to make a 9(b) motion.
15 I'm going to read the complaint.

16 MS. MAINIGI: Could I offer a suggestion, your Honor?

17 THE COURT: Yes.

18 MS. MAINIGI: There are a few grounds besides 9(b)
19 also on which we would move to dismiss. I wholly agree with
20 you. I hate to have my client go through tremendous amounts of
21 discovery if there is a possibility, which I think there is, of
22 dismissal here, in my humble opinion. I'm happy, and certainly
23 others may want to weigh in, to do some sort of expedited
24 briefing for you or something that gets you our arguments in a
25 more boiled-down fashion, a letter brief, or something of the

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1 sort. We would just like the opportunity to be heard in the
2 context of dismissal because we do think it is a waste of a
3 colossal amount of resources to go through discovery on a case
4 where the relators have completely failed to articulate one
5 single particular fact as it relates to several of the
6 defendants.

7 THE COURT: But that's 9(b).

8 MS. MAINIGI: That's 9(b), and there are some
9 technical issues related to the False Claims Act that may also
10 be at issue, whether it's certification issues, and there are
11 motion to dismiss arguments.

12 THE COURT: If you're going to make motions, make
13 motions and make them on your own schedule, and you will take
14 discovery while I am deciding them because they will go into
15 the queue. There is a long queue. They will go into my
16 motions queue. I cannot guarantee that they will rise to the
17 top of the queue, but you will be taking discovery. This is
18 not the PSLRA. I do not have to stay discovery while I decide
19 a motion to dismiss. We will be aiming toward an April 1, 2015
20 trial date.

21 MS. MAINIGI: Your Honor, is there some means to
22 expedite at least your looking at the 9(b) argument through
23 submission of a letter brief or something?

24 THE COURT: Sure. The 9(b) argument can be looked at
25 by pulling out the complaint and taking it on the airplane when

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1 I leave this afternoon, and instead of watching HGTV on Jet
2 Blue, I will read the complaint.

3 MS. MAINIGI: Okay, your Honor.

4 THE COURT: It's time for me to read the complaint.

5 Yes, sir.

6 MR. MERON: Thank you, your Honor. Very quickly. As
7 with CVS, we will move not just under 9(b), but with respect to
8 9(b), the one respect in which a letter brief might prove
9 useful is there are various elements of the antikickback
10 statute and the False Claims Act that we believe have to be
11 specifically pled, sort of like a checklist, did they plead
12 this, did they plead that, that reading the complaint alone --

13 THE COURT: That's not 9(b). That's 12(b)(6). 9(b)
14 is the pleading of fraud.

15 MR. MERON: You have to plead the specifics of the
16 fraud, who, what, where, and when. And what the case law says,
17 if there is a predicate allegation because there has been a
18 violation of antikickback statute, for example, you have to
19 plead each of the elements of the antikickback statute with
20 particularity.

21 THE COURT: Give me a citation for that. I'm actually
22 trying to save your clients money.

23 MR. MERON: I don't have a citation for that, your
24 Honor.

25 THE COURT: That's what I would need because I would

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1 like to read that case.

2 MR. MERON: We would like to make an expedited letter
3 brief to get you very quickly the elements of what has to be
4 shown so when you look at the complaint, you can see for
5 yourself the elements are not there. For example, one doctrine
6 in this circuit, as well as in others, is that you have to at a
7 minimum plead the specific, identify specific false claims that
8 were submitted. So with respect, for example, to Curascript,
9 one of my clients, there's not a single specific false claim
10 pled. Not one. And so we're entitled to dismissal. Accredo,
11 the same way. And with respect to the amendment issue, your
12 Honor, there are, first of all, a number of courts that have
13 said you're already facing a second amended complaint, so the
14 amendment now would be the third amended complaint, after two
15 and a half years, a lot of government investigation, you
16 certainly have discretion, No. 1, to make a dismissal at this
17 point with prejudice.

18 THE COURT: I do, but I'll give them one more because
19 I haven't done anything so far.

20 MR. MERON: But what the courts in this circuit do
21 say, and the Second Circuit has said and other courts have
22 said, is that what 9(b) is precisely designed to avoid is a
23 plaintiff who comes in, supposed to be a whistleblower,
24 supposed to have inside information, not pleading it
25 sufficiently, then taking discovery, conducting a fishing

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1 expedition.

2 THE COURT: You're not telling me anything I don't
3 know. I've been sitting here for 18 years, 15 years. So
4 you're not telling me anything that's new to me. I'm
5 suggesting that there is an expedited, cost-efficient way for
6 me to decide that issue, and it is to read the pleading.

7 MR. YU: Your Honor, very briefly, I just want to be
8 very clear. The government, venn diagram, the government's
9 only remaining claims are against Novartis.

10 THE COURT: Novartis, I understand.

11 MR. YU: We wholeheartedly agree with the Court's
12 point about the complaint. We think the complaint certainly
13 has all the details. One point to bear on this, the government
14 filed effectively the same set of allegations with respect to
15 Myfortic last April. That's when we initially intervened. And
16 at that point, we actually disclosed the same theories as part
17 of our initial disclosures. At that point, Novartis did not
18 file a motion to dismiss. They actually answered. So at this
19 point, for there to be an argument somehow the notice which
20 apparently was present last year no longer pertains today is
21 surprising to us, and we really think if the Court were to read
22 the complaint, you would see that there's more than ample
23 evidence in there. Of course, if there are any issues, we'll
24 be glad to address them. We'll be glad to explain the
25 certification issue that we had explained earlier.

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1 THE COURT: The certification issue is of peculiar
2 importance in the drugstores because they're the ones who have
3 to certify to Medicare and Medicaid because they're the ones
4 who dispense the drugs and then ask the government for the
5 money back. And, again, forgive my ignorance, I don't know
6 what the certification issue is with respect to Novartis.
7 Novartis is the alleged facilitator of the fraud, but what is
8 Novartis certifying?

9 MR. YU: Your Honor, the certification is a false
10 statement or false record.

11 THE COURT: But does Novartis certify something to the
12 federal government?

13 MR. YU: Novartis caused, by engaging this fraud --

14 THE COURT: It simply aids and abets in the false
15 certification by the pharmacies, it's an aider and abettor?

16 MR. YU: Actually, Novartis caused the pharmacy, by
17 offering and agreeing to specifically and by conspiring --

18 THE COURT: This is a simple factual statement I'm
19 going to make, you tell me true or false. Novartis does not
20 file with the Department of Health and Human Services a
21 document that you allege to be a false certification in this
22 case, true or false?

23 MR. YU: True, your Honor. The case is not by
24 Novartis itself. It's what Novartis caused others --

25 THE COURT: We call that aiding and abetting.

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1 MR. YU: Your Honor, I was simply trying to refer to
2 the statute. I was trying to refer back to the statute, the
3 False Claims Act.

4 Your Honor, that's our view of the 9(b) issue. We are
5 certainly glad to explain our view of the law, but we think the
6 complaints offer more than enough specificity.

7 THE COURT: I'll tell you what. If you all have
8 something that you want to call to my attention so that I am an
9 informed reader of the complaint, do it by the end of next week
10 and then just let me read the complaint. Mr. Chesler is
11 jumping up. Cravath can't possibly do anything that simple.

12 MR. CHESLER: Unfortunately, your Honor, our sin is in
13 the past.

14 THE COURT: You've already made a motion.

15 MR. CHESLER: Exactly, and I was simply rising to say
16 so.

17 THE COURT: You're not going to ask me to read any
18 more than that.

19 MR. CHESLER: I'm not, your Honor.

20 MS. MAINIGI: That's fine with us, your Honor.

21 MR. CHESLER: Indeed, your Honor, I would suggest on
22 your question about the cases that on pages seven to ten to our
23 brief, we've cited a number of the case to which counsel have
24 alluded. That is why I was rising. Unfortunately, my client
25 is here to hear that we've already spent their money filing the

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1 brief we otherwise wouldn't have filed.

2 THE COURT: It's okay. I just think that if we're
3 going to have a 9(b) dismissal and one last shot, I should just
4 read the pleadings with an informed eye and to do it.

5 I think I'll leave it at that for today, which means
6 that if we go forward, let's assume that the people at the
7 front table get it right -- and you, ladies and gentlemen on
8 the telephone, good morning. I'm so sorry, I know you're
9 there. I wish you were here, except it's cold in New York. So
10 let me assume that they get it right, what will accompany the
11 denial of the motion to dismiss will be a discovery schedule
12 set by me. But to inform that, what are we looking at in terms
13 of discovery? On this one, I always ask the defendant first
14 and then the plaintiff.

15 MR. CHESLER: Thank you, your Honor. We had, prior to
16 today, submitted a proposed case management order in the
17 government cases. There's a separate one which has a little
18 complexity to it in the relator case, which I'll come to.

19 THE COURT: I've already told you that in the relator
20 case, we're going to pretend that three of the drugs don't
21 exist until I've litigated the rest of it.

22 MR. CHESLER: Yes, your Honor.

23 With respect to the government case, let me go there,
24 and obviously we've heard your Honor loud and clear about your
25 views on scheduling, I just wanted to point out that in that

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1 proposed case management order, there was a proposal for all
2 discovery to be completed by next July.

3 THE COURT: July of 2015?

4 MR. CHESLER: Yes, your Honor. And I should say I'm
5 actually, as a defense lawyer, typically a big fan of getting
6 it done faster because my view is I'm going to be more ready
7 than plaintiffs are, so I'm not standing to say there's some
8 religious problem with a trial in April versus finishing
9 discovery in July. The only concern I have, and I rise to say
10 it, is it goes back to our point, they tell us that there are,
11 I think the phrase is 20, dozens, I've forgotten how many they
12 say, pharmacists who supposedly were involved in this scheme,
13 none of whom, but for the ones who are here, are even named.
14 They say that there were thousands of false claims.

15 THE COURT: Presumably what you really want to find
16 are the physicians whose minds were allegedly changed by
17 pharmacists or whose orders were overridden somehow by a
18 pharmacist.

19 MR. CHESLER: I was come to go that one last, your
20 Honor. I started with the pharmacists most of whom are not
21 named, claims virtually none of which are identified,
22 physicians not one of whom is named, not one. So if they're
23 out there, these pushovers that supposedly listened to the
24 pharmacies and give people lifesaving drugs because somebody
25 else tells them to, we don't know who they are. In terms of

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1 the discovery, the reason I say that we ended up agreeing with
2 the government to a date in July was the theory was that by
3 then, presumably with the aid of Magistrate Judge Francis, we
4 were going to get the discovery we need and we were going to
5 get the specifics we need if they can provide them. If they
6 can't, we're done. If they can provide them, we're going to
7 get them sooner rather than later and we're going to be able to
8 get the discovery done in that time. That's why we submitted a
9 July date.

10 MS. MAINIGI: Your Honor, with respect to discovery,
11 if it continues, I think our theme is smaller is better. We
12 are the un-intervened case, and the allegations are few and far
13 between. If they somehow manage to survive the motion to
14 dismiss, they will still be few and far between, so our goal is
15 to not take 50 depositions or anywhere close to that. If they
16 want to do that in the intervening case, they can knock
17 themselves out, but in the un-intervening case, we want to go
18 small because that's what that case deserves.

19 THE COURT: Mr. Ross and Mr. Miller, let me ask what
20 role in discovery the AGs anticipate. Assuming we go forward,
21 we're not going to have depositions with 11 different assistant
22 Attorneys General participating, are we?

23 MR. ROSS: No, your Honor. The way I guess we've
24 looked at it is that Mr. Miller will attend those depositions
25 on behalf of the states that are joined in the multistate

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1 complaint. I would be doing it on behalf of California, and
2 then there's the State of Washington.

3 THE COURT: Because California is such a special
4 place, it's so big, it needs its own guy at the table?

5 MR. ROSS: It's California.

6 THE COURT: It's California, yes.

7 MR. ROSS: So we envision it would likely be just the
8 two of us.

9 MR. MILLER: Your Honor, I'll say also we did a joint
10 investigation with the U.S. Attorney's office with respect to
11 Exjade and we expect to cooperate with them and coordinate for
12 efficiency in discovery.

13 THE COURT: Okay.

14 MR. YU: Your Honor, just addressing the question of
15 timing, we're certainly happy to move quickly. One of the
16 concerns, and I'll come back to some of the issues Mr. Chesler
17 raised, we're happy to move quickly. One of the concerns which
18 we raised earlier this week is on Myfortic, there are a lot of
19 pharmacies, a lot of documents and the company. During the
20 intervention, we investigated to figure out whether there's a
21 scheme to intervene on. Now we're in discovery, so we're
22 trying to get a comprehensive understanding.

23 THE COURT: Wait a minute. You're trying to get a
24 comprehensive understanding? You've been at this for two and a
25 half years. You're trying? Excuse me. I don't buy that.

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1 Here's the rule for the government: You've been looking at
2 this for two and a half years, you would continue to look at it
3 if I hadn't stopped you. As far as I'm concerned, you know
4 what you've got to know. You're not going to get extra time.
5 You are on the hook.

6 MR. YU: Your Honor, we are certainly not asking for
7 extra time.

8 THE COURT: You're not going to get it. I'm telling
9 you, as far as I'm concerned, as a taxpayer, there's nothing
10 else for you to discover. You've already spent a lot of my
11 taxpayers dollars investigating this. Presumably you know what
12 your case is about. You signed a complaint under Rule 11.

13 MR. YU: Yes, your Honor.

14 THE COURT: You shouldn't be looking for witnesses.
15 And you will be required within 15 days of the decision denying
16 the motion to dismiss to identify -- to identify -- the
17 physicians who were deluded, the pharmacists who were deluded.
18 You're not going to go looking for them. You better know who
19 they are now. There's nothing that makes me more upset as an
20 old lawyer who has not forgotten what it was to represent a
21 client, even after 18 years, almost 19, oh, my God. Nothing
22 makes me madder than to have somebody, a plaintiff, who is the
23 government and who has been investigating with subpoena power
24 and all the powers the government has, for two and a half
25 years, to stand up and say we have to now find out. You don't

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1 have to find out anything. You've found it all out. You have
2 to tell them.

3 MR. YU: Your Honor, in this case, the point I was
4 making was there are outstanding discovery requests for
5 documents. We asked earlier this week how soon those could be
6 responded to, so we don't yet have an end date from the
7 company. As soon as we can get a sense of when the discovery
8 and when the document discovery will be complete --

9 THE COURT: I'm really not interested in their
10 discovery to you, although there will be some, but your
11 discovery to them.

12 MR. YU: Yes, your Honor.

13 THE COURT: The government's bound by Rule 11, too.

14 MR. YU: Yes, of course, your Honor. And the
15 complaint, as alleged, in the complaint, we identify, we
16 identify the pharmacies and the part of the scheme, and so
17 here, we're certainly ready to move quickly.

18 THE COURT: Good, because I know who they want to
19 depose. They want to talk to these doctors who were deluded.

20 MR. YU: Right.

21 THE COURT: They want to talk to the pharmacists
22 themselves. Presumably you have a list of who these people
23 are.

24 MR. YU: Your Honor, we have provided the lists to the
25 defendants, so that's the point I was trying to get to.

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1 THE COURT: You've already given them those names.

2 MR. YU: They have those names. Not only do they have
3 the names on Myfortic, they have numerous documents. They have
4 many, many faxes where pharmacies e-mailed the recommendations,
5 or, I'm sorry, obviously it's a fax, faxed recommendations of
6 physicians and physicians signed off on the switching behavior.
7 So it's certainly simply contrary to the record to suggest that
8 Novartis does not know the physicians or the pharmacies that
9 are involved. We named the specific pharmacies.

10 THE COURT: Good. If that's true, then there's not a
11 big problem, but I just want to suggest that if the government
12 thinks that the unsealing of this complaint was the equivalent
13 of filing the first indictment, which I'll refer to as the
14 investigatory indictment, in a large case where there are going
15 to be six superseders, no, not going to happen. Your
16 investigation is over.

17 MR. YU: Your Honor, we fully understand that, and,
18 again, our purpose here is to make sure that whatever discovery
19 remains to be done for the government, we'll go ahead and do it
20 as quickly as possible.

21 THE COURT: Good.

22 MR. YU: And we'll get ready for trial.

23 THE COURT: The government, by the way, has a perfect
24 right to weigh in also by the end of next week with anything
25 that it wants to weigh in on in defense of its pleading. The

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1 same with the relator. Again, I think the way to decide a 9(b)
2 motion is to read the pleadings.

3 MR. SUBRAMANIAN: Your Honor, if I could just add one
4 thing, for the relator complaint, we have no idea what
5 arguments the defendants may make. There's been no motion
6 filed. I would just ask that if we're going to submit
7 anything, it would be one week after theirs.

8 THE COURT: Fine.

9 MR. SUBRAMANIAN: One other thing I want to clarify,
10 as to the three other drugs, Gleevec, Tesigna, and TOBI, those
11 should be sort of left in the icebox for the time being.

12 THE COURT: I would put them in the icebox. I want to
13 litigate this.

14 MR. SUBRAMANIAN: The only thing I would add is CVS
15 Caremark isn't part of the alleged scheme as to Exjade, which
16 is the overlap drug. Maybe they can sit on the sidelines, they
17 don't really need to be litigating that part of the case.

18 THE COURT: You're not in Myfortic?

19 MS. MAINIGI: We're not in Myfortic, your Honor, but
20 we'd like to still file our papers next week. We want out. We
21 want out.

22 THE COURT: I get that. I get that.

23 All right. It will be interesting and I have good
24 lawyers and that always makes me happy, so thank you. As you
25 know, it should be abundantly clear, I have a whole lot to

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1 learn, but you have been very helpful and I will be reading the
2 antikickback statute on the plane this afternoon and hoping
3 I'll learn something.

4 Thank you, all. Thank you, folks, on the telephone
5 for patiently listening.

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